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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,739	CHRISTIANS, FREDERICK C.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *5-12,14-19 and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 13, 20, 28 and 29* is/are rejected.

7)☒ Claim(s) *3,4 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05, 11/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending.
Claims 5-12, 14-19, and 21-27 are withdrawn.
Claims 1-4, 13, 20, and 28-30 are examined on the merits.

Election/Restrictions

1. Applicant's election without traverse of the invention of group I (claims 1-21 and 28-30) in the reply filed on 07/06/2006 is acknowledged. Applicant's further election of the specific combination of Tag sequences SEQ ID NO: 242-261, 263-282, and 284-290, as well as the election of the Tag gene of SEQ ID NO: 2059 (which comprises the TagI gene, see also the Response to Restriction filed 04/30/2006).

2. Claims 5-12, 14-19, and 21-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (i.e. methods for analyzing gene expression, and DNA molecules specifically requiring non-elected SEQ ID NOs), there being no allowable generic or linking claim.

Priority

The instant application claims priority to US Provisional application 60/395,530 filed 07/12/2002, however this provisional application does not contain any basis for the nucleotide sequences of the 20-mer Tag sequences of SEQ ID NOs: 1-2050. Thus the filing date of claims requiring any of SEQ ID NOs: 1-2050 is the filing date of the instant application which is 07/14/2003.

Claim Objections

3. Claims 3, 4, and 30 are objected to because of the following informalities:

Claims 3, 4, and 30 each repeat the listing of SEQ ID NO: 2059 such that 2059 appears twice in the listings of Tag gene sequences.

Claim 4 contains a period in middle of the claim after the listing of Tag gene SEQ ID NOs. See MPEP 609.01(m).

Appropriate correction is required.

Claims 2, 3, 4, 29 and 30 are objected to because they specifically recite non-elected subject matter. The claims recite non-elected SEQ ID NOs of 'Tag sequences' and 'Tag genes'. Applicant has elected for the examination of the claims in so far as they require the specific combination of Tag sequences SEQ ID NO: 242-261, 263-282, and 284-290, as well as the election of the Tag gene of SEQ ID NO: 2059. Prior to allowance of these claims, the non-elected subject matter will be required to be deleted from the claims.

Duplicate Claims Warning

4. Applicant is advised that should claim 3 be found allowable, claims 4, 13, and 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, claim 3 (consonant with the Election) is drawn to a DNA molecule comprising SEQ ID NO: 2059. Because SEQ ID NO: 2059 contains an SphI site, a T3 promoter comprising SEQ ID NO: 2067, 21 consecutive A residues, a PstI site, and a T7 promoter comprising SEQ ID NO: 2068 in an orientation opposing the T3 promoter, claims 4, 13, and 30 (which are also drawn to DNA molecules comprising SEQ ID NO: 2059) claim the same nucleic acid molecule without further limitation.

Claim Rejections - 35 USC § 112 2nd - Indefiniteness

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1, 3, 4, 20 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, 20, and 28 are unclear over recitation of the terms 'Tag' in reference to sequences, genes, and transcripts. The term 'Tag' is not an art recognized term for any particular nucleic acid sequence or specific genus of sequences, nor does the specification provide a clear definition of what is encompassed by the term 'Tag', thus the metes and bounds of the DNA molecule claimed are unclear.

Claim 3 is unclear over recitation of the phrase 'wherein said Tag gene is selected from the group consisting of SEQ ID NO: 2059'. The sequence of SEQ ID NO: 2059 is 1073 nts in length and includes a T3 promoter, 940 nts of 'Tag gene', 21 consecutive A residues, and a T7 promoter on the opposite strand as said T3 promoter.

Because all of these elements are also individually listed separate from the 'Tag gene' in claim 1, from which claim 3 depends, it is unclear if applicant in fact intends to claim a DNA molecule with, for example, two copies of the T3 promoter, two copies of the T7 promoter, and two poly A sites having at least 21 consecutive A residues.

Claim 4 is unclear over recitation of the phrase 'said Tag gene is selected from the group consisting of SEQ ID NO: 2059'. The sequence of SEQ ID NO: 2059 is 1073 nts in length and includes a T3 promoter, 940 nts of 'Tag gene', 21 consecutive A residues, and a T7 promoter on the opposite strand as said T3 promoter. Because all of these elements are also individually listed separate from the 'Tag gene' in claim 1, from which claim 4 depends, it is unclear if applicant in fact intends to claim a DNA molecule with, for example, two copies of the T3 promoter, two copies of the T7 promoter, and two poly A sites having at least 21 consecutive A residues.

Claim Rejections - 35 USC § 112 1st – Written Description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 13, 20, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at www.uspto.gov).

The rejected claims 1 and 20 are drawn DNA molecules comprising restriction endonuclease sites, promoters, 'Tag genes' comprising at least 5 20 mer 'Tag sequences', and a poly(A) site. Claim 13 requires only that the DNA molecule of claim 1 comprise SEQ ID NO: 2059. Claim 28 requires only a DNA molecule comprising a 'Tag gene" comprising at least 5 'Tag sequences'. The claims do not set forth any structural requirements of the claimed DNA molecules, nor do the claims or the specification clearly define any structural limitations regarding what is encompassed by a 'Tag sequence' or a 'Tag gene'.

When the claims are analyzed in light of the specification, the instant invention encompasses an enormous number of nucleic acid probes and primers comprising a wide variety of nucleic acid sequences. The claims encompass any nucleic acid sequence that is a 'Tag gene' comprising any 'Tag sequences'. In the case of claims 1 and 20, the nucleic acid need only contain at least 5 'Tag sequences' wherein the 'Tag sequences are 20 mers'. Claim 13 further limits claim 1 by requiring only that the molecule of claim 1 comprises SEQ ID NO: 2059, but claim 13 does not particularly set forth any limitations regarding the required 'Tag gene'. Claim 28 requires only that the 'Tag gene' comprises 5 'Tag sequences' with no requirements concerning the length of the 'Tag sequences'. The claims are thus drawn to a multitude of nucleic acid sequences that encompass an extremely large genus. The claims do not clearly define the nucleotide sequence information or structural limitations regarding what is

considered a 'Tag gene' or a 'Tag sequence'. Nucleic acids of such a large genus have not been taught by the specification.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. The instant specification provides SEQ ID NOs: 1-2050 as 'Tag sequences' that are each 20 nucleotides in length, and further teaches SEQ ID NOs: 2051-2066 as 'Tag genes' comprising multiple 'Tag sequences'.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other than nucleotide sequence or position within a particular gene), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, while the specification provides a functional description of the provided 'Tag sequences' (i.e. selected from all possible 20mers to have similar hybridization characteristics and minimal homology to sequences in the public databases; p.7) and references to general methods to identify a 'Tag sequence' (i.e. reference to US Patent 6,458,530), there is no indication as to how one may *a priori* identify a nucleic acid sequence of any particular length as a 'Tag sequence' that can comprise a 'Tag gene'. Additionally, even the functional description of the provided 'Tag sequences' allows for a large degree of variability with the inclusion of the phrases 'similar hybridization characteristics' and 'minimal homology', which, depending upon the interpretation of these phrases, allows for the inclusion of any other 20mers, in addition to the provided SEQ ID NO: 1-2050, from the collection of all possible 20mers.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, the provided information regarding the specific 'Tag sequences' of SEQ ID NO: 1-2050 and the particular 'Tag sequences' SEQ ID NO: 2051-2066 do not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed by the claimed methods, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a statement that nucleic acids with a particular qualtiy are part of the invention and reference to a potential method for their identification. The nucleic acid sequences are required.

In conclusion, the limited information provided regarding the particular 'Tag sequences' of SEQ ID NO: 1-2050 and the particular 'Tag genes' of SEQ ID NO: 2051-2066 provided in the instant specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a nucleic acid molecules comprising any 'Tag sequences' and 'Tag genes' at the time the application was filed.

Thus, having considered the breadth of the claims and the provisions of the

specification, it is concluded that the specification does not provide adequate written description for the claims.

Claim Rejections - 35 USC § 102

In the rejection of claims under 35 USC § 102 the breadth of the claims is noted. The claims are drawn to DNA molecules comprising a 'Tag gene' comprising 'Tag sequences'. However there is no clear definition in either the specification or the art as to the structural limitations or requirements attributed to either a 'Tag gene' or a 'Tag sequence'. Thus in examination of the claims, the terms 'Tag gene' and 'Tag sequence' are interpreted as broadly encompassing any nucleic acid sequence.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 20 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Domier et al 1989 as evidenced by GenBank GI:58064 (1990).

Domier et al teaches a DNA molecule that is a plasmid for transcription of the TVMV RNA using a T3 promoter (p.3510, right col.; Fig. 2) in which a cDNA of the complete TVMV genome, including a poly(a) tail of 96 nts, is cloned into a pBluescript vector.

Regarding claim 1, the reference teaches a DNA molecule comprising the required elements in a 5' to 3' direction. The DNA molecule pBS1220 (Fig 2) has a T3 promoter followed by the complete TVMV sequence that is approximately 9500 nucleotides in length. Given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the TVMV sequence is a Tag gene comprised of at least 5 20 mer Tag sequences. The reference further teaches that the TVMV cDNA sequence includes a poly(A) tail of 96 A residues (Fig 2B; p.3511, right col., first full paragraph). Additionally the reference teaches an SstI restriction site preceding a T7 promoter in on the opposite strand as the T3 promoter. Regarding the limitation of a first restriction endonuclease site preceding the T3 promoter, while the reference does not specifically indicate the sequence preceding the T3 promoter the reference does teach that the plasmid is generated from pBluescript KS(-) which contains a TaqI site preceding the T3 promoter sequence (as evidenced by nucleotides 792-795 of GenBank GI:58064, which is the pBluescript KS(-) sequence).

Regarding claim 20, the reference teaches that the pBS1220 plasmid contains three BglII sites.

Regarding claim 28, given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the TVMV sequence in the pBS1220 plasmid is a Tag gene comprising at least 5 Tag sequences.

11. Claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Samartzidou et al (US Patent 6,943,242 filed 5/7/2002 with priority to provisional application 60/289,202 filed 5/7/2001).

Samartzidou et al teaches nucleic acid molecules for controls in gene expression analysis systems.

Regarding claim 28, given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the sequence of YIR1 (SEQ ID NO: 1 of Samartzidou et al) is a DNA molecule comprising a Tag gene comprising at least 5 Tag sequences.

Claim Rejections - 35 USC § 103

In the rejection of claims under 35 USC § 103 the breadth of the claims is noted. The claims are drawn to DNA molecules comprising a 'Tag gene' comprising 'Tag sequences'. However there is no clear definition in either the specification or the art as to the structural limitations or requirements attributed to either a 'Tag gene' or a 'Tag sequence'. Thus in examination of the claims, the terms 'Tag gene' and 'Tag sequence' are interpreted as broadly encompassing any nucleic acid sequence.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Domier et al 1989 as evidenced by GenBank GI:58064 (1990) in view of Affymetrix CD-ROM P/N 610026 (2000) and Samartzidou et al (US Patent 6,943,242 filed 5/7/2002 with priority to provisional application 60/289,202 filed 5/7/2001).

Domier et al teaches a DNA molecule comprising the required elements in a 5' to 3' direction. The DNA molecule pBS1220 (Fig 2) has a T3 promoter followed by the complete TVMV sequence that is approximately 9500 nucleotides in length. Given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the TVMV sequence is a Tag gene comprised of at least 5 20 mer Tag sequences. The reference further teaches that the TVMV cDNA sequence includes a poly(A) tail of 96 A residues (Fig 2B; p.3511, right col., first full paragraph). Additionally the reference teaches an SstI restriction site preceding a T7 promoter in on the opposite strand as the T3 promoter. Regarding the limitation of a first restriction endonuclease site preceding the T3 promoter, while the reference does not specifically indicate the sequence preceding the T3 promoter the reference does teach that the plasmid is generated from pBluescript KS(-) which contains a TaqI site preceding the T3 promoter sequence (as evidenced by nucleotides 792-795 of GenBank GI:58064, which is the pBluescript KS(-) sequence). Thus Domier et al teaches a DNA molecule satisfying all of the limitations of claim 1, from which the rejected claim 2 depends.

Domier et al does not teach a DNA molecule in which the 'Tag sequences' are SEQ ID NO: 242-261, 263-282, and 284-290.

The specification of the instant application teaches that SEQ ID NO: 1-2050, which are provided as 20mer 'Tag sequences' are selected from all possible 20mers to have similar hybridization characteristics and minimal homology to sequences in the public databases (page 7 of specification). The GeneChip GenFlex Tag Array Technical Note 1 (2001) describes CD-ROM P/N 610026 as providing Tag sequences

that were selected from a set of 20mers with closely matched melting temperatures and not containing sequences in the public databases (section Sequence Selection) and contains 2050 Tag sequence (section – Tag performance). Additionally, Fig 5 of the GeneChip GenFlex Tag Array Technical Note 1 (2001) presents 19 20 mer sequences that are identical to SEQ ID NOs: 2001-2019 of the instant application. The MPEP in chapter 2100 states:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the examination of the instant application, based on the teachings of the instant specification, the PTO has basis for believing that CD-ROM P/N 610026 contains the sequences of SEQ ID NOs: 1-2050.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have incorporated any number of any of the Tag sequences taught by CD-ROM P/N 610026, including the Tag sequences identical to SEQ ID NO: 242-261, 263-282, and 284-290 or their complements, into the DNA molecule of Domier et al. One would have been motivated to use any of the sequences of CD-ROM P/N 610026 based on the assertion of the GeneChip GenFlex Tag Array Technical Note 1 that such nucleotide sequences represent sequences that are not found in the public databases and the teachings of Samartzidou et al that desirable controls for gene expression analysis do not hybridize to any known gene or EST (col.1 lns.60-61; col.6 lns.13-15). One would have been motivated to put any of the CD-ROM

P/N 610026 sequences in to the DNA molecule of Domier et al because Samartzidou et al teaches that control DNA sequences can be cloned in to a vector for in vitro transcription of a control mRNA with a poly(A) tail (col.6 lns.16-25) and Domier et al teaches a DNA molecule from which a particular sequence with a poly(A) tail may be transcribed in vitro (p.3510, right col., In vitro transcription).

14. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samartzidou et al (US Patent 6,943,242 filed 5/7/2002 with priority to provisional application 60/289,202 filed 5/7/2001) in view of Affymetrix CD-ROM P/N 610026 (2000).

Samartzidou et al teaches nucleic acid molecules for controls in gene expression analysis systems. Given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the sequence of YIR1 (SEQ ID NO: 1 of Samartzidou et al) is a DNA molecule comprising a Tag gene comprising at least 5 Tag sequences. Thus Samartzidou et al teaches all of the limitations of claim 28, from which the rejected claim 29 depends.

Samartzidou et al does not teach a DNA molecule in which the 'Tag sequences' are SEQ ID NO: 242-261, 263-282, and 284-290.

The specification of the instant application teaches that SEQ ID NO: 1-2050, which are provided as 20mer 'Tag sequences' are selected from all possible 20mers to have similar hybridization characteristics and minimal homology to sequences in the public databases (page 7 of specification). The GeneChip GenFlex Tag Array

Technical Note 1 (2001) describes CD-ROM P/N 610026 as providing Tag sequences that were selected from a set of 20mers with closely matched melting temperatures and not containing sequences in the public databases (section Sequence Selection) and contains 2050 Tag sequence (section – Tag performance). Additionally, Fig 5 of the GeneChip GenFlex Tag Array Technical Note 1 (2001) presents 19 20 mer sequences that are identical to SEQ ID NOs: 2001-2019 of the instant application. The MPEP in chapter 2100 states:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the examination of the instant application, based on the teachings of the instant specification, the PTO has basis for believing that CD-ROM P/N 610026 contains the sequences of SEQ ID NOs: 1-2050.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used any number of any of the Tag sequences taught by CD-ROM P/N 610026, including the Tag sequences identical to SEQ ID NO: 242-261, 263-282, and 284-290 or their complements, to create a control sequence as taught by Samartzidou et al. One would have been motivated use any of the sequences of CD-ROM P/N 610026 based on the assertion of the GeneChip GenFlex Tag Array Technical Note 1 that such nucleotide sequences represent sequences that are not found in the public databases and the teachings of Samartzidou et al that

desirable controls for gene expression analysis do not hybridize to any known gene or EST (col.1 lns.60-61; col.6 lns.13-15).

15. Claim 2 is provisionally rejected under 35 U.S.C. 103(a) as being obvious over Domier et al 1989 as evidenced by GenBank GI:58064 (1990) in view of Mittmann et al copending Application No. 09/827,383 (filed 04/04/2001 with priority to Provisional application 60/195,585 filed 04/06/2000) which has a common Assignee with the instant application and Samartzidou et al (US Patent 6,943,242 filed 5/7/2002 with priority to provisional application 60/289,202 filed 5/7/2001). Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Domier et al teaches a DNA molecule comprising the required elements in a 5' to 3' direction. The DNA molecule pBS1220 (Fig 2) has a T3 promoter followed by the complete TVMV sequence that is approximately 9500 nucleotides in length. Given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the TVMV sequence is a Tag gene comprised of at least 5 20 mer Tag sequences. The reference further teaches that the TVMV cDNA sequence includes a poly(A) tail of 96 A residues (Fig 2B; p.3511, right col., first full paragraph). Additionally the reference teaches an SstI restriction site preceding a T7 promoter in on the opposite strand as the T3 promoter. Regarding the limitation of a first restriction endonuclease site preceding

the T3 promoter, while the reference does not specifically indicate the sequence preceding the T3 promoter the reference does teach that the plasmid is generated from pBluescript KS(-) which contains a TaqI site preceding the T3 promoter sequence (as evidenced by nucleotides 792-795 of GenBank GI:58064, which is the pBluescript KS(-) sequence). Thus Domier et al teaches a DNA molecule satisfying all of the limitations of claim 1, from which the rejected claim 2 depends.

Domier et al does not teach a DNA molecule in which the 'Tag sequences' are SEQ ID NO: 242-261, 263-282, and 284-290.

Mittmann et al teaches the sequences of SEQ ID NO: 1-2050 which are identical to SEQ ID NO: 1-2050 of the instant application. Mittmann et al teaches that SEQ ID NO: 1-2050 are 20mer Tag sequence selected from a set of 20mers with closely matched melting temperatures and not containing sequences in the public databases (p.7 lns.12-16).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have incorporated any number of any of the Tag sequences taught Mittmann et al, including the Tag sequences identical to SEQ ID NO: 242-261, 263-282, and 284-290 or their complements, into the DNA molecule of Domier et al. One would have been motivated use any of the sequences of Mittmann et al based on the teachings of Mittmann et al that such nucleotide sequences represent sequences that are not found in the public databases and the teachings of Samartzidou et al that desirable controls for gene expression analysis do not hybridize to any known gene or EST (col.1 lns.60-61; col.6 lns.13-15). One would have been motivated to put

any of the sequences taugh by Mittmann et al into the DNA molecule of Domier et al because Samartzidou et al teaches that control DNA sequences can be cloned in to a vector for in vitro transcription of a control mRNA with a poly(A) tail (col.6 lns.16-25) and Domier et al teaches a DNA molecule from which a particular sequence with a poly(A) tail may be transcribed in vitro (p.3510, right col., In vitro transcription).

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

16. Claim 29 is provisionally rejected under 35 U.S.C. 103(a) as being obvious over Samartzidou et al (US Patent 6,943,242 filed 5/7/2002 with priority to provisional application 60/289,202 filed 5/7/2001) in view of Mittmann et al copending Application No. 09/827,383 (filed 04/04/2001 with priority to Provisional application 60/195,585 filed 04/06/2000) which has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35

U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Samartzidou et al teaches nucleic acid molecules for controls in gene expression analysis systems. Given the broadest reasonable interpretation of the terms 'Tag gene' and 'Tag sequence', the sequence of YIR1 (SEQ ID NO: 1 of Samartzidou et al) is a DNA molecule comprising a Tag gene comprising at least 5 Tag sequences. Thus Samartzidou et al teaches all of the limitations of claim 28, from which the rejected claim 29 depends.

Samartzidou et al does not teach a DNA molecule in which the 'Tag sequences' are SEQ ID NO: 242-261, 263-282, and 284-290.

Mittmann et al teaches the sequences of SEQ ID NO: 1-2050 which are identical to SEQ ID NO: 1-2050 of the instant application. Mittmann et al teaches that SEQ ID NO: 1-2050 are 20mer Tag sequence selected from a set of 20mers with closely matched melting temperatures and not containing sequences in the public databases (p.7 lns.12-16).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used any number of any of the Tag sequences taught by Mittmann et al, including the Tag sequences identical to SEQ ID NO: 242-261, 263-282, and 284-290 or their complements, to create a control sequence as taught by Samartzidou et al. One would have been motivated use any of the sequences of Mittmann et al based on the teachings of Mittmann et al that such nucleotide sequences represent sequences that are not found in the public databases

and the teachings of Samartzidou et al that desirable controls for gene expression analysis do not hybridize to any known gene or EST (col.1 lns.60-61; col.6 lns.13-15).

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion and Claim Objection

17. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. Although the 'Tag sequences' of SEQ ID NO: 1-2050, and any combinations of any number of SEQ ID NO: 1-2050 are obvious in view of the prior art cited in this office action (i.e. the prior art of CD-ROM P/N 610026 which teaches the sequences and the associated Technical Note that teaches that the sequences are not found in public databases, and the prior art of Samartzidou et al that teaches desirable qualities of a nucleic acid for array hybridization controls), claim 30 requires a nucleic acid comprising SEQ ID NO: 2059 which contains specific sequence elements (e.g. T3

promoter, a poly(A) site of 21 consecutive A residues, and T7 promoter), only some of which are obtained from the pSport1 vector (GenBank GI:531828) in addition to a particular combination of 47 20mers selected from SEQ ID NO: 1-2050 in a particular order. SEQ ID NO: 2059 is a 1073 nucleotide sequence that comprises 47 consecutive 20mer sequences (SEQ ID NO: 242-261, 263-282, and 284-290) from position 55-994. However, to arrive at the complete sequence of SEQ ID NO: 2059 would require, for example, the replacement of nucleotides 231-252 of the pSport1 sequence with the 47 particular 20mer Tag sequences in the specific order, and the insertion of a T3 promoter sequence after nucleotide 202 of the pSport1 sequence, and the replacement of nucleotides 272-279 of the pSport1 sequence with a poly(A) site of 21 consecutive A residues. And while the cloning of DNA molecules used for transcription templates into plasmids, the use of T3 promoters for transcription, and in vitro transcription of poly(A) tails using poly(A) sites encoded in the DNA template were known in the art, the prior art does not teach or suggest the particular combination of elements to arrive at the specific sequence of SEQ ID NO: 2059. There is no motivation in the prior art for the particular placement of a T3 promoter or poly(A) with respect to the placement of the sequence of the 47 consecutive Tag sequences within the pSport1 vector.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jehanne Sitton

JEHANNE SITTON
PRIMARY EXAMINER
8/21/06